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(71) Applicant
Olicon A/S

(Incorporated in Denmark)

20 E Mileparken, DK 2740 Skovlunde, Denmark

(72) Inventors
Donald Selwyn Painter
Margaret Jagla(74) Agent and/or Address for Service
Keith W Nash & Co
Pearl Assurance House, 90-92 Regent Street,
Cambridge, CB2 1DP(51) INT CL.
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Selected US specifications from IPC sub-class
B29C**(54) Making hearing aids**

(57) A hearing aid shell is made by inserting a flexible membrane (28) into the ear and introducing a light curable acrylic resin to fill the space between a central core (10) and the membrane (28) thereby pushing the membrane (28) into contact with the surface of the ear cavity. The core is shaped to impart to the shell a void for accepting an electronics cartridge. The core (10) is transparent and curing of the resin is carried out by a hand-held light source. The shell can be rapidly custom made at a hearing aid centre, ready to be fitted with a standard electronics cartridge to make a hearing aid.

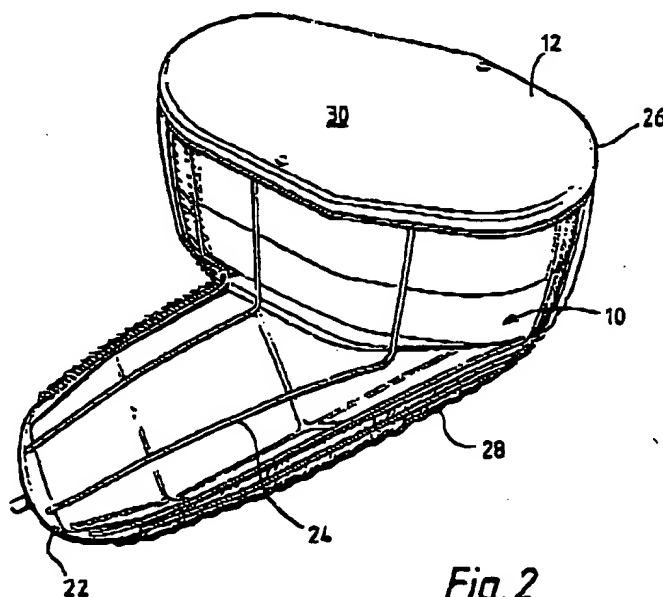


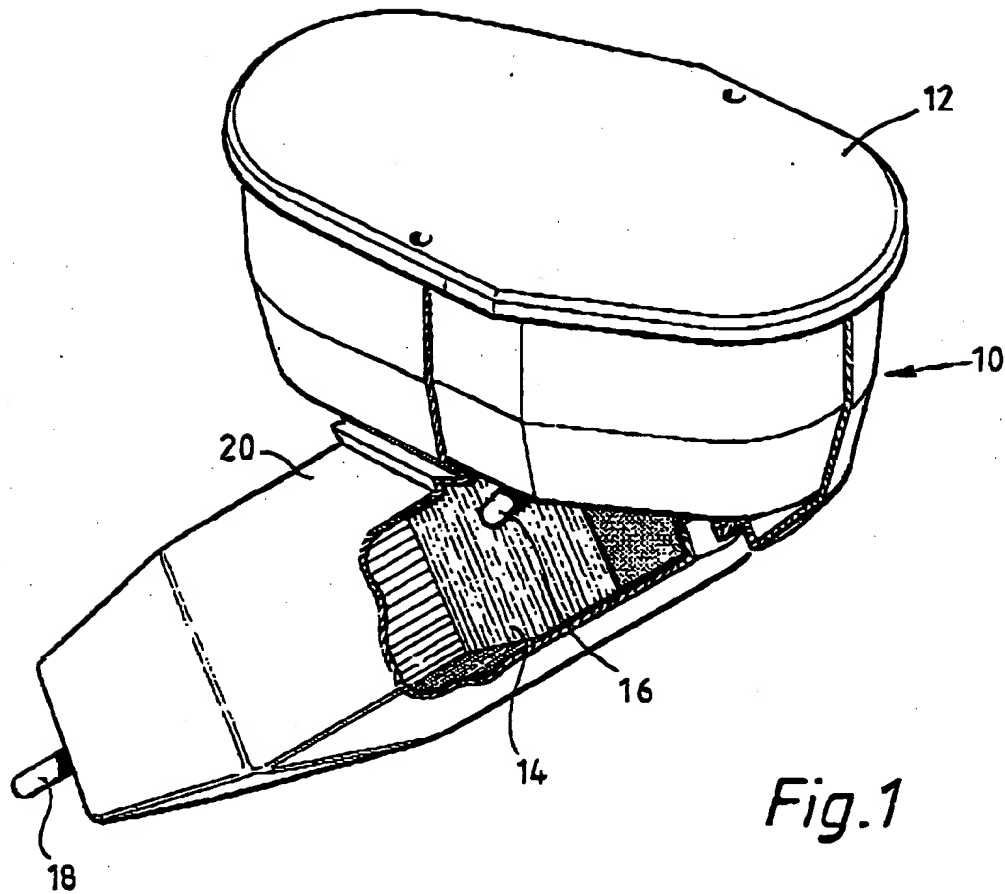
Fig. 2

The drawing(s) originally filed was (were) informal and the print here reproduced is taken from a later filed formal copy.
The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1982.

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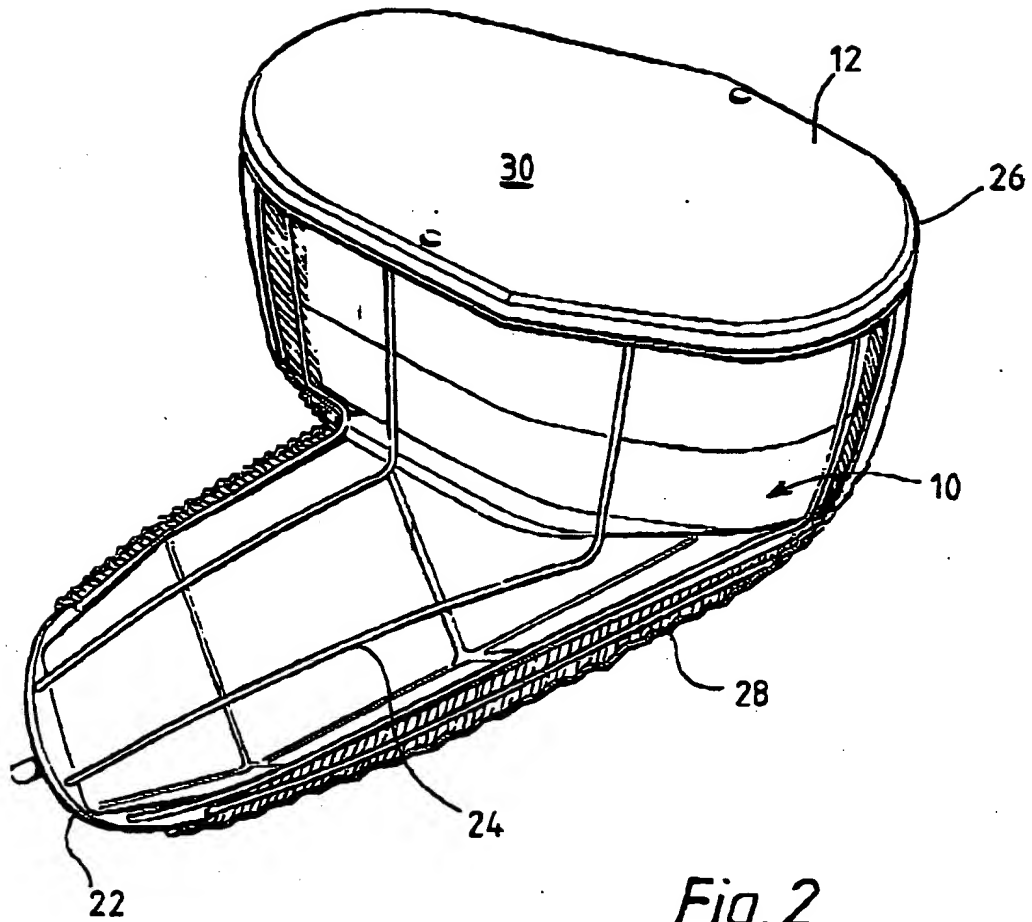
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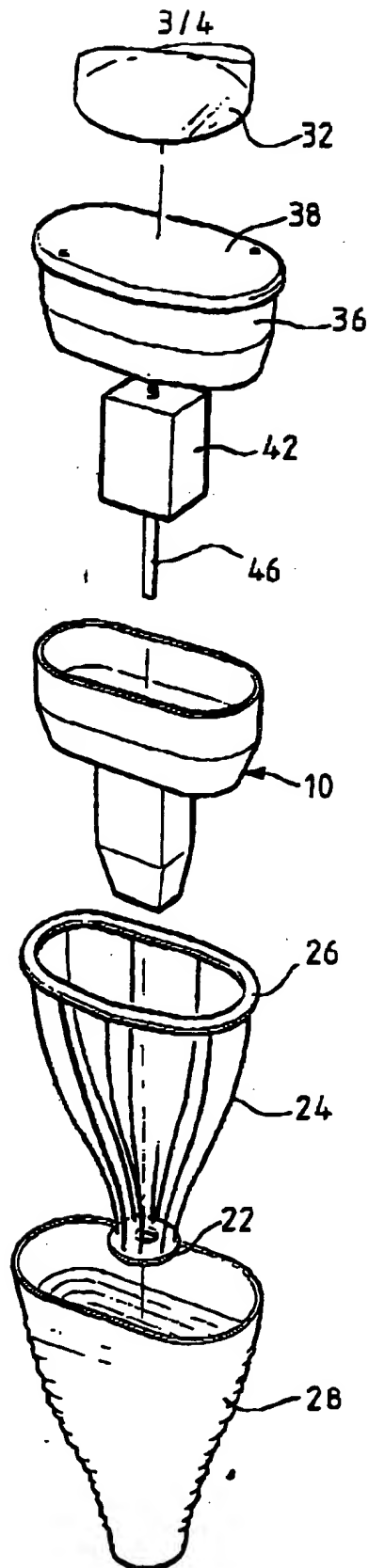
*Fig. 1*

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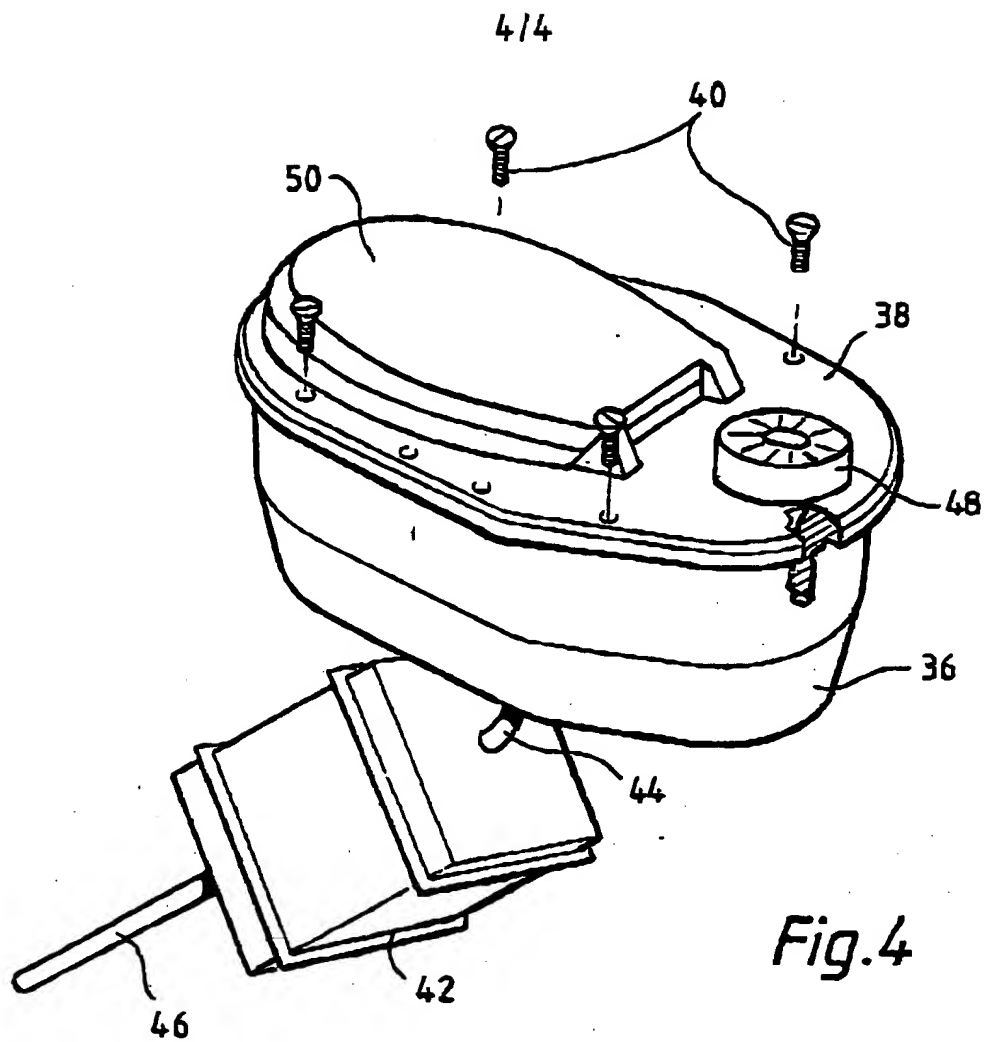
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*Fig. 3*

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Hearing Aids

Field of the invention

This invention relates to methods of making hearing aids and to the resulting hearing aids.

Background to the invention

Traditionally hearing aids have been worn behind the ear, with a sound-conducting tube connected to an earmould placed in the concha and meatus of the hearing-impaired. More recently miniaturisation has allowed the electro-acoustic components to be incorporated into the earmould (in-the-ear hearing aids), filling out partly or wholly the concha; further developments have allowed the size to be diminished, such that the entire earmould/hearing aid is substantially retained within the meatus, with only a minor proportion protruding into the concha (canal aids).

The canal aid has two main advantages: the acoustics are beneficial to the user (due to diffraction around the pinna), and the aid is inconspicuous in use.

At present there are two techniques to manufacture canal aids:

1. Based on an accurate impression of the individual ear, a shell is cast in acrylics (or produced in metal by electroplating), and the electro-acoustic components installed in this individually produced

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shell.

2. The aid is manufactured in a standard case resembling a typical ear canal and is either inserted directly in the ear canal, or fitted with one of several size "ear adaptors" (standard earmoulds).

The former is referred to as a custom-made canal aid, and the latter as a stock canal aid.

The custom-made canal aid has the disadvantage that it is manufactured to the individual ear, normally by a specialist manufacturer. Therefore a long time elapses between obtaining the impression of the ear and delivery of the finished aid, and the customer must place an order without having tried the aid; furthermore a custom-made hearing aid tends to be expensive to manufacture.

- The stock aid may not be a comfortable fit in the ear canal, since the earmould is not made to the individual ear. For the same reason adequate acoustical seal between ear canal and aid is difficult to achieve, frequently resulting in acoustical feed-back due to the short distance between the locus of the amplified sound and the microphone.

Summary of the invention

According to one aspect of the invention a method of making a shell of a hearing aid comprises inserting a flexible walled membrane into the ear, introducing a synthetic plastics material into the space within the ear lined by the membrane so that the plastics material is moulded to the shape of the ear lined by the membrane,

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causing or allowing the plastics material to set, removing the set body of plastics material and the membrane from the ear, disposing of the membrane and using the set body as the shell of an in-the-ear hearing aid. The plastics material may be a light curable acrylic resin, in which case light is applied to the plastics material to cause it to cure and set in the ear, or the plastics material may be a two component chemically curable acrylic resin. In either case, the shell is moulded in the patient's ear, and by choosing the membrane to be a thin plastics material the shell will be an accurate impression of the shape of the ear cavity. The shell can be made rapidly at the hearing aid centre, ready to be fitted to a standard electronics cartridge (or module) having transducers, an amplifier and a battery. The shell can be fitted with a replacement electronics cartridge very easily at a later stage.

To accept such a standard electronics cartridge, the shell is preferably moulded with a central void, conveniently resulting from the inclusion of a core during moulding of the shell, the plastics material filling the space between the core and the membrane lining the ear. The core is shaped to impart to the shell a void for accepting the electronics cartridge, and the core may thus be regarded as a dummy electronics cartridge.

When the plastics material is a light curable acrylic resin, the core is preferably made from a transparent material to enable curing to be achieved by the application of a hand-held light source which directs light through the core to the curable acrylic resin.

The core may comprise a first block for forming at the

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outer end of the shell a main part of the void to receive a microphone, battery and electronic circuitry of the electronics cartridge. The core may also comprise a second block for forming at the inner end of the shell a subsidiary part of the void to receive a loudspeaker of the electronics cartridge, and form a base for an exchangeable wax guard. Preferably, the first and second blocks are interconnected by a flexible spine and by bellows, the spine and the bellows enabling the core to be manipulated to a shape to suit the shape of the ear, prior to moulding.

It is desirable for the shell to have vent holes to avoid occlusion felt by the user and allow for low frequency signals coming directly to the eardrum for the escape of ear emissions. Such vent holes are preferably incorporated into the shell at the moulding stage by fitting, into the space between the membrane and the core, strands in the form of wires or tubes which are removed after moulding of the shell to leave vent holes extending from the inner end of the shell to the outer end thereof.

According to another aspect of the invention there is provided a shell of a hearing aid made according to said one aspect, and also for a hearing aid including such a shell

A method of making a hearing aid will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a core used in moulding a shell of the hearing aid,

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Figure 2 is a perspective view of the core of Figure 1 fitted with a vent hole assembly and surrounded by an outer flexible membrane,

5 Figure 3 is an exploded view of the parts of Figure 2, and

Figure 4 shows an electronic cartridge which is fitted to the shell of the hearing aid.

10 The shell for the hearing aid is moulded in the patient's ear at a hearing aid centre. Moulding is carried out around a central core 10 (or dummy cartridge) which is shown in Figure 1 and which is incorporated in order to provide in the resulting shell a void or recess to receive a standard electronics cartridge which will be described with reference to Figure 4.

15 The dummy cartridge can be made either as described below or supplied as a set of different rigid dummies representing the necessary range of angles.

Referring to Figure 1, the core 10 has a first block 12 and a second block 14 interconnected by a flexible wire spine 16. The blocks 12 and 14 are of a transparent
20 plastics material, eg acrylic. A tube 18 projects from the block 14, and the blocks 12 and 14 are also linked by a flexible wall 20 which may be a bellows. The flexibility of the spine 16 and the wall 20 enables the
25 core 10 to be manipulated by bending into a shape in which it is best suited to the shape of the patient's ear. It may be desirable to have two shapes of core available at the hearing aid centre, one shaped for right ears and the other shaped for left ears.

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A vent tube assembly is then fitted around the core 10, as illustrated in Figure 2. The vent tube assembly comprises an oval end plate 22 from which extend flexible tubes or strands 24 interconnected at the remote end of the assembly by a flange plate 26 attached to the block 12. The core and vent tube assembly is then surrounded by an outer flexible membrane 28, eg of latex rubber, and the complete assembly illustrated in Figure 2 is inserted into the patient's ear. Alternatively, the membrane 28 may first be placed in the ear and then the core and vent tube assembly inserted into the part of the ear lined by the membrane 28.

In another variation of the process, the strands 24 may be attached to the outer surface of the dummy cartridge before insertion into the ear and curing of the resin. When the dummy cartridge is removed, the strands can be pulled from their embedded positions leaving the vents on the inner surfaces of the outer shell. In yet another variation the use of strands to form vents is omitted during the shell making process, and the necessary vents are produced on the inner surface of the moulded shell by a machining operation.

A light curable acrylic resin, in a plastic condition, is introduced into the space between the core 10 and the membrane 28. The acrylic resin flows into and fills the space, pushing the wall of the membrane 28 into contact with the surface of the ear cavity, which thus acts as a mould to shape the acrylic resin to the shape of the ear cavity as lined by the membrane 28.

Light is introduced to cure and set the acrylic plastics,

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this being done by applying to the exposed end 30 of the transparent core light from a portable hand-held unit diagrammatically indicated at 32 in Figure 3. Light is typically applied for between 30 seconds and 2 minutes to
5 cure and set the acrylic resin.

Once the acrylic plastics has set, the whole assembly is removed from the ear, and the outer membrane 28, vent tube assembly and core 10 are separated, leaving a shell with an outer shape complimentary to that of the patient's ear,
10 and an inner void corresponding to the shape of the core 10. The shell has vent holes defined by the strands 24.

The shell may then be polished and dipped in a finishing lacquer or into a visible light curing acrylic plastics to add to the moulded shell a surface layer compensating for
15 the thickness of the membrane 28, and also giving a fine smooth and durable finish to the shell.

A standard electronics cartridge, shown in Figure 4, is then fitted to the shell to complete the hearing aid. The electronics cartridge has a housing 36 accommodating a
20 microphone, battery and electronics. The housing 36 is closed by a face plate 38 having a projecting flange with holes for attaching the cartridge to the outer edge of the moulded shell by screws 40. The underside of the flange is undercut to register with the outer ends of the vent
25 holes of the shell. The electronics cartridge also comprises a speaker housing 42 linked to the housing 36 by a flexible tube 44 enclosing wiring. A tube 46 projects from the speaker housing 42. The tube 46 may incorporate a thin membrane to prevent ear emissions reaching the
30 electronics. A user operated volume control knob 48 projects from the face plate 38, and a removable cover 50

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encloses a battery compartment.

In an alternative arrangement (not illustrated) a moulded mounting ring is glued to the outer opening of the finished shell and provides a mechanism for snap fitting the electronics cartridge into place, avoiding the need for the screws 40 in Figure 4.

It will be appreciated that in fitting the electronics cartridge to the moulded shell, the tube 46 projects through the hole in the shell defined by the tube 18 of the core 10, that the loudspeaker housing 42 fits in the void of the shell left by the block 14, and that the housing 36 fits in the void in the shell left by the block 12.

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Claims

1. A method of making a shell of a hearing aid, comprising inserting a flexible walled membrane into the ear, introducing a synthetic plastics material into the space within the ear lined by the membrane so that the plastics material is moulded to the shape of the ear lined by the membrane, causing or allowing the plastics material to set, removing the set body of plastics material and the membrane from the ear, disposing of the membrane and using the set body as the shell of an in-the-ear hearing aid.
2. A method according to claim 1, wherein the plastics material is a light curable acrylic resin, and light is applied to the plastics material to cause it to cure and set in the ear.
3. A method according to claim 1, wherein the plastics material is a two component chemically curable acrylic resin.
4. A method according to any of the preceding claims, wherein to accept a standard electronics cartridge, the shell is moulded with a central void, resulting from the inclusion of a core during moulding of the shell, the plastics material filling the space between the core and the membrane lining the ear.
5. A method according to claims 2 and 4, wherein the core is made from a transparent material to enable curing to be achieved by the application of a hand-held light source

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which directs light through the core to the curable acrylic resin.

6. A method according to claim 4 or 5, wherein the core comprises a first block for forming at the outer end of the shell a main part of the void to receive a microphone, battery and electronic circuitry of the electronics cartridge.

7. A method according to claim 6, wherein the core also comprises a second block for forming at the inner end of the shell a subsidiary part of the void to receive a loudspeaker of the electronics cartridge, and form a base for an exchangeable wax guard.

8. A method according to claim 7, wherein the first and second blocks are interconnected by a flexible spine and by bellows, the spine and the bellows enabling the core to be manipulated to a shape to suit the shape of the ear, prior to moulding.

9. A method according to any of claims 4 to 8, wherein vent holes are incorporated into the shell at the moulding stage by fitting, into the space between the membrane and the core, strands in the form of wires or tubes which are removed after moulding of the shell to leave vent holes extending from the inner end of the shell to the outer end thereof.

10. A method of making a shell of a hearing aid, substantially as herein particularly described with reference to the accompanying drawings.

11. A shell of a hearing aid made according to any of

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claims 1 to 10.

12. A hearing aid including a shell according to claim
11.